THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

January 27, 2014

Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

Re: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals Proposed Rule[1]

Docket No. FDA–2011–N–0143

Dear Sir or Madam:

On July 29, 2013, the Food and Drug Administration (FDA or the Agency) published in the Federal Register a proposed rule entitled Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (the "Proposed Rule"). The Proposed Rule would require importers to help ensure that food imported into the United States is produced in compliance with the processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under the hazard analysis and risk-based preventive controls and standards for produce safety sections of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling. The Food Marketing Institute (FMI) appreciates the opportunity to comment on this important matter.

FMI proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

[1] 78 Fed. Reg. 45730 (July 29, 2013).

FMI supported the enactment of the Food Safety Modernization Act (FSMA). We believe the regulations issued to implement section 301 of FSMA, if crafted in a manner consistent with the following comments will enhance public health and strengthen our nation's food safety regulatory system.

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I. Auditing

Option 1 Will Enhance the Global Food Safety System and Result in Lower Costs for Retailers and Other Importers than Option 2

FDA has set forth two options regarding the requirements for foreign supplier verification activities. Under Option 1, for the importation of food with hazards controlled by foreign suppliers that are reasonably likely to cause serious adverse health consequences or death to humans or animals (SAHCODHA), the importer would be required, at a minimum, to conduct or obtain the results of an annual onsite audit to ensure that the foreign supplier is adequately addressing the hazards. In other situations involving less serious hazards, importers would have more flexibility to choose an appropriate supplier verification method.

Under Option 2 of the Proposed Rule, importers would have to select a verification activity from among onsite auditing, sampling and testing, review of the supplier's food safety records, or some other appropriate procedure, taking into account the risk presented by the hazard in the food, the probability that the exposure to the hazard will result in serious harm, and the food and supplier's status of compliance with U.S. food safety requirements.

FMI believes that Option 1 will enhance the global food safety system and result in lower costs for retailers and other importers than Option 2.

Option 1 Will Result in Lower Costs for Retailers and Other Importers

If the Agency adopts Option 1, then foreign facilities and farms producing food intended for consumption in the U.S. that control SAHCODHA hazards will be required to be audited no less than annually to ensure that such hazards are adequately controlled. Pursuant to § 1.506(g)(3) (under both options), onsite audits are required to consider the FDA food safety regulations that apply to the food and the foreign supplier. Therefore, any foreign exporter seeking to export product for consumption in the U.S. that controls SAHOCDHA hazards will be required to have an onsite audit annually for applicable FDA food safety regulations.

From a logistical standpoint, this degree of standardization will make FSVP implementation simpler and less costly for retailers who deal with thousands of different types of food from suppliers across the globe. Retailers and wholesalers will not have to evaluate and go back and forth with each supplier on whether or not an audit is necessary for SAHCODHA hazards the importer controls. The audit must consider the

relevant FDA food safety regulations applicable to the foreign supplier, thus obtaining the audit report will be the simplest and most effective means of ascertaining compliance for retailers and other importers. Retailers and wholesalers simply don't have the resources to assess on a product-by-product and hazard-by-hazard basis whether or not an audit is necessary for SAHCODHA hazards controlled by foreign suppliers. Average profit margins in the industry are less than one percent and it is not economically feasible or retailers and wholesalers evaluate whether Option 1 or Option 2 is appropriate on a hazard-by-hazard and product-by-product basis. By requiring an annual audit be conducted, the decision is made for them and the foreign exporter. An annual onsite audit for SAHCODHA hazards will become the standard for foreign exporters, which will simplify compliance for U.S. importers that import thousands or tens of thousands of different items such as retail supermarkets. Such standardization will reduce costs. FMI understands that in certain situations, conducting onsite auditing alone may not be sufficient to ensure that the hazard is adequately controlled. Regardless of this fact, Option 1 still offers a consistency of process not found in Option 2.

Option 1 is More Implementable for Retailers, Other Small Businesses and Foreign Suppliers

Retailers and wholesalers who import product generally import a wider range of product than other firms who import in the food industry. One retailer may import thousands of different items including produce, processed foods, prepared foods, ingredients and dairy products. Having to decide on a product-by-product basis—and the regulatory and legal risks associated with that decision—as to whether each control for a SAHCODHA hazard controlled by the foreign supplier should be verified by an onsite audit is simply unworkable. If Option 1 is adopted then essentially all exporters controlling SAHCODHA hazards reasonably likely to occur will be required to have an annual onsite audit. Retailers will then be able to rely on this audit for conducting their FSVP activities and assessing whether or not further verification should be taken. As one audit annually of a foreign supplier can effectively satisfy all of that supplier's importers, Option 1 will be less expensive for U.S. importers and will potentially reduce costs for foreign suppliers as the standardization of process will limit the burdens associated with FSVP compliance on an importer-by-importer basis.

Option 1 Will Reduce Duplicative Auditing and Testing

If Option 1 is adopted, it will obviate the need for duplicative verification across the various importers. For example, Importer 1 may choose to have an audit conducted for SAHCODHA hazards A, B, and C controlled by the foreign supplier, but decides that SAHCODHA hazards D and E do not necessitate onsite auditing to verify their control. Instead, that importer decides to conduct a sampling and testing program for hazards D and E. Importer 2 begins sourcing from the same foreign supplier after Importer 1 and

requires that control of hazard D be verified by an onsite audit in addition to hazards A-C, and that hazard E be verified by review of food safety records. The foreign supplier now is subject to a second audit and an additional request for records. Shortly thereafter Importer 3 begins sourcing from the supplier and conducts redundant testing and sampling for hazard E because documentation of the sampling and testing conducted by Importer 1 is kept internally by Importer 1 and not available to Importer 3.

Rather than having redundant sampling and testing and other verification activities conducted amongst the various importers sourcing from the foreign supplier, Option 1 would require an annual onsite audit for all SAHCODHA hazards controlled by the foreign supplier that are reasonably likely to occur. A single audit report could satisfy all of the importers sourcing from the foreign supplier. This would reduce overall costs to the economy by minimizing redundancies in verification and reduce the burdens foreign exporters would face in dealing with U.S. importers on a hazard-by-hazard, importer-by-importer basis.

Option 1 Enhances Global Food Safety

FMI believes there is simply no substitute for annual onsite audits. In the absence of an annual audit, suppliers may get complacent and food safety practices may deteriorate. An unannounced, annual audit will provide a strong incentive to foreign exporters to maintain robust food safety programs. In addition, ownership and management of foreign facilities and farms may change without notification to the importer and FMI members have seen the effectiveness of food safety programs vary greatly from one year to the next at a facility or farm due to a change in management or ownership. Only an onsite audit at a regular frequency will detect such changes.

Option 1 is Consistent with Global Food Safety Initiative Standards

The Global Food Safety Initiative (GFSI) requires all benchmarked food safety schemes to conduct onsite auditing.[2] Option 1 is consistent with this requirement. Option 2 does not require onsite audits. Establishing a verification system that is inconsistent with GFSI will create confusion and could lead to a weakening of the global food safety system as firms abandon auditing to match the baseline set by FDA.
FMI owns the Safe Quality Food Institute (SQF)—a GFSI-benchmarked scheme. On January 6, 2014, SQF announced the incorporation of an unannounced audit protocol to be included in the next version of the SQF Code, becoming the first internationally-accredited food safety standard to do so. FMI believes that each facility should be constantly “audit-ready” and prepared for an assessment every day and the changes to the SQF Code will result in this. We believe that Option 1, with annual unannounced audits will similarly achieve this result.

[2] GFSI Guidance Document, Version 6.3, Part II, Section 3.5 (October 2013).

Consistency with International Standards

FMI believes that FDA should, to the greatest extent possible consistent with the requirements of FSMA, craft the Proposed Rule in such a manner as to provide for audits conducted pursuant to existing global food safety standards to satisfy the requirements of foreign supplier verification. Mandating that farms and food facilities receive an additional redundant audit would impose unnecessary costs and compliance burdens. To the greatest degree permissible under FSMA, FDA should permit existing food safety programs and audits to satisfy compliance requirements without adding additional regulatory burdens to the supply chain.

Audits Conducted for Mandatory Import Certifications and the Voluntary Qualified Importer Program Should be Permitted to be Relied upon for Purposes of Foreign Supplier Verification

FMI agrees that audits conducted for purposes of certifying foods for mandatory import certifications and facilities for the Voluntary Qualified Importer Program should be permitted to be relied upon for purposes of foreign supplier verification.

FMI Agrees that Importers Should be Able to Rely on Previously Conducted Audits

FMI concurs with FDA that obtaining a previously conducted timely audit can satisfy the requirements of foreign supplier verification under the Proposed Rule. We support the Agency's statement that: "It is not our intent to increase the number of audits of each foreign supplier; rather, we anticipate there will be consolidation of audits."[3]

Auditing Standards

FMI believes that the auditing standards are adequate but seeks clarification as to what requirements foreign suppliers must be audited for. Under § 1.502, importers must develop, maintain and follow an FSVP that provides adequate assurances that the foreign supplier is producing food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (preventive controls) or 419 (produce safety), if either is applicable and is producing food in compliance with sections 402 (adulteration) and 403(w) (misbranding with respect to allergen labeling). These four sections represent only part of the

[3] 78 Fed Reg. 45755.

obligations exporters of food to the U.S. are required to comply with. The Proposed Rule requires audits to "consider the FDA food safety regulations, if any, that apply to the food and foreign supplier."[4]

FMI seeks clarity regarding the auditing requirements. Although FDA explicitly states in the Proposed Rule that importers are not required to consider intentionally introduced hazards,[5] foreign facilities are clearly required to comply with the Food Defense regulations issued pursuant to FSMA. Because auditors would be required to consider FDA food safety regulations that apply to the foreign supplier, would this mean auditors would need to audit for compliance with the Food Defense Rule? If so, would this mean that if Option 2 is adopted by the Agency, would potentially never be audited and therefore never have any audit for Food Defense Rule compliance?

Use of Accredited Auditors

FDA states that:

> . . . even after FDA has implemented section 808 and importers begin using accredited third-party auditors to provide verification of their foreign suppliers in accordance with the FSVP regulations, we believe that it would be acceptable for an importer to rely on an audit conducted by a third-party auditor who is a qualified individual but is not accredited in accordance with section 808. We invite comment on whether, at some future date and/or under particular circumstances, importers should no longer be permitted to rely on third-party auditors who are not accredited in accordance with section 808 to conduct onsite audits or other FSVP activities.[6]

FMI believes that FDA should permit importers to use existing global food safety standards based on hazard analysis and critical control points (HACCP) principles and the auditors that audit to those standards for purposes of FSVP onsite audits.

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[4] Section 1.506(g)(3) (for both Option 1 and 2).

[5] We also tentatively conclude that it is appropriate to require importers to consider only those hazards that occur naturally or may be unintentionally introduced. Intentional hazards raise different issues and concerns. We plan to address the issue of certain intentionally introduced hazards as part of our rulemaking to implement section 106 of FSMA (codified in section 420 of the FD&C Act (21 U.S.C. 350i)), which directs FDA to issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points. 78 Fed. Reg. 45748.

[6] 78 Fed. Reg. 45744.

Option 1 Provides Greater Regulatory Certainty for Smaller Firms

Option 1 provides greater regulatory certainty for all businesses, but particularly smaller firms and importers that import thousands of different items. Rather than evaluating whether audits are necessary for SAHCODHA hazards controlled by foreign suppliers on a supplier-by-supplier, item-by-item, hazard-by-hazard basis, and face the associated liability under the FD&C Act[7], the regulatory obligation will be clear: the importer will have to conduct an audit or obtain the documentation of a previously conducted one. Under Option 1, importers will not have to be concerned about making the decisions on whether or not to conduct an audit for the SAHOCODHA hazards controlled by their foreign suppliers and documenting the justification for such decisions.

II. Definition of the Term Importer

In the supermarket industry, retailers and wholesalers may act as importers themselves, or may purchase product after it has already been entered into the U.S. FMI seeks greater clarity as to the definition of the term importer in the Proposed Rule. The definition differs from the definition of "importer of record" contained within the Tariff Act.[8]

FSVP v. Prior Notice Regulations and Customs Definitions

The Proposed Rule defines the term importer as:

> The person in the United States who has purchased an article of food that is being offered for import into the United States. If the article of food has not been sold to a person in the United States at the time of U.S. entry, the importer is the person in the United States to whom the article has been consigned at the time of entry. If the article of food has not been sold or consigned at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry.[9]

The previous definition differs from that contained within the Tariff Act. Pursuant to the Tariff Act, an importer of record has the right to make entry. Importer of record is

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[7] The importation or offering for importation of a food if the importer does not have in place a foreign supplier verification program in compliance with section 805 (21 USCS § 384a) is a prohibited act under the FD&C Act and violators are subject to criminal penalties. 21 USC § 331(zz).
[8] 19 USC ch. 4.
[9] 78 Fed. Reg. 45772.

defined as the owner or purchaser of merchandise, or consignee, or a licensed customs broker when designated by the owner or purchaser or consignee.[10]

FMI seeks greater clarification as to the differences between the two definitions. A term "FSVP importer" may be helpful for the Agency to use in guidance documents or the regulation itself to make the distinction clear.

One key difference appears to be that a licensed customs broker cannot be appointed by a U.S. purchaser or U.S. consignee to serve as the FSVP importer by mere virtue of the fact that the person holds such a license. However, a licensed customs broker could be separately appointed as an agent or representative of a foreign owner or consignee in the circumstance where there is no U.S. buyer or consignee.

FMI seeks greater clarity as to the meaning of the term purchased. U.S. Customs and Border Protection (CBP) defines the terms owner and purchaser to include any party with a financial interest in a transaction, including, but not limited to, the actual owner of the goods, the actual purchaser of the goods, a buying or selling agent, a person or firm who imports for exhibition at a trade fair or a person or firm who imports foods for repair or alteration etc.[11]

The terms owner or purchaser would not include a nominal consignee who effectively possesses no other right, title, or interest in the goods, except as he possessed under a bill of lading, air waybill, or other shipping document.[12]

FMI seeks clarity regarding FDA's use of the term purchaser. Does FDA have a similar conception as CBP of what is a purchaser for purposes of FSVP? FMI notes that the statute uses the term owner and not purchaser in defining importer for purposes of FSVP and seeks information from FDA as to whether the agency differentiates between those two terms.[13]

Private Label Products

Retailers may contract with foreign manufacturers to produce private label product bearing their logo outside of the U.S. They then purchase the product from a U.S. importer after it has been entered into the U.S. FMI seeks clarity that in such a transaction, a retailer would not be deemed to be an importer by mere virtue of the fact

[10] 19 USC 1484(a)(2)(B).
[11] Customs Directive No. 3530-002A.
[12] Id.
[13] 21 USC 384a(2).

that their name appears on the label of the product being offered for import. FMI does not believe that such a retailer should be considered an importer.

Agents/Representatives of Foreign Suppliers

FMI seeks clarity as to whether the agent/representative appointed pursuant to the FSVP Rule for purposes of conducting supplier verification in circumstances where there is no U.S. buyer or consignee is the same agent that is designated for purposes of sec. 415 Bioterrorism Act Food Facility Registration. If not, FMI seeks more information as to how such agent/representative is appointed. Will such agent/representative be registered with FDA? Furthermore when is a "United States agent" for purposes of FSVP is different from a "representative of foreign owner?"

III. Rules of Origin

FSVP v. Prior Notice Rules and Customs Definitions

FMI seeks clarity as to how the term "foreign supplier" in the Proposed Rule differs from the term "manufacturer" as it is used in FDA's rules for prior notice requirements as well as how the term "manufacturer" is defined by CBP.

On Customs Form 7501, the term manufacturer is the invoicing party(ies) (except for textiles where it is the actual manufacturer). Country of origin is the country of manufacture, production or growth of any article. If an item consists of material produced, derived from, or processed in more than one country, it shall be considered a product of that country where it last underwent a substantial transformation.[14]

Under FDA's prior notice regulations, country of production means for an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the U.S. For an article of food that is no longer in its natural state, it is the country where the article was made.[15] Under these regulations, manufacturer means the last facility that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a de minimis nature. If the food undergoes further manufacturing/processing that exceeds an activity of a de minimis nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.[16] Grower is

[14] Customs Form 7501 Instructions.
[15] 21 CFR 1.276.
[16] Id.

defined as "a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both."[17]

Under the Proposed Rule, foreign supplier is defined as the establishment that manufacturers/processes the food, raises the animal, or harvests the food that is exported to the U.S. without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature.[18]

FMI seeks clarification regarding the definition of foreign supplier in the Proposed Rule and how it compares to the definition of manufacturer and grower under the FDA prior notice regulations. The term "foreign supplier" includes both farms and processing and packing facilities. Do the terms "grower" and "manufacturer" collectively equate to the term "foreign supplier." Consistency between the prior notice regulations and FSVP regulations will simplify compliance.

FMI also seeks clarity as to how importers should distinguish the "further manufacturing/processing" from the concept of "substantial transformation" applied by CBP.

Regulation of Food Contact Substances

The prior notice regulations specifically exclude food contact substances from prior notice requirements.[19] The definition of food in the Proposed Rule does not exclude food contact substances, only pesticides as defined in 7 U.S.C. 321(ff). FMI seeks confirmation that food contact substances[20] are indeed subject to the Proposed Rule. If this is indeed the case, FMI urges the Agency to provide guidance as to how verification of food contact substances should be conducted as they generally low risk.

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[17] Id.

[18] 78 Fed. Reg. 45772

[19] (4) Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)),
(i) Except for purposes of this subpart, it does not include:
(A) Food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)), or
(B) Pesticides as defined in 7 U.S.C. 136(u).
21 CFR 1.227.

[20] As defined in 21 USC 348(h)(6).

IV. Hazard Analysis and Evaluation

Definition of Term Hazard Reasonably Likely to Occur

It is important that the Proposed Rule provide that both likelihood and severity need to be considered in a scientific hazard analysis, consistent with international standards. For example, as outlined in Codex HACCP guidelines, the selection and management of controls requires consideration of two important elements: severity and probability. By considering both severity and probability (or likelihood), facilities are able to successfully evaluate the significance of potential hazards on a case-by-case basis, determine the appropriate control measures, and decide how such measures need to be managed. Significantly, it is very common to consider the contributions of prerequisite programs—many of which FDA will likely want to regulate as preventive controls—in deciding a hazard is not reasonably foreseeable. This approach encourages strong food safety programs and aligns with FSIS precedent.

Transportation Practices

The Proposed Rule requires the hazard analysis to evaluate transportation practices on the safety of the finished food for the intended consumer.[21] The food facility then has an obligation to identify and implement preventive controls to minimize or prevent the hazards identified in the analysis. FMI seeks clarity regarding the applicability of the Sanitary Food Transportation Act (SFTA) regulations to product in transit intended for consumption in the U.S.

FMI believes the following excerpt from the preamble to the seafood HACCP is relevant to the Proposed Rule:

> When processors accept raw materials for processing, especially from vessels, they assume some responsibility for the condition of the incoming materials, regardless of how others are regulated. This is true under both general commercial law and the laws administered by FDA. Carriers likewise have responsibilities. If a carrier fails to exercise such controls as are necessary, food that it carries may be rendered adulterated and the owner of the product, i.e., the processor, could suffer product loss. …..While these regulations exempt carriers and harvest vessels from direct coverage, experience with the application of a mandatory HACCP program may, at some later date, cause the Agency to reconsider its approach…….

FMI believes SFTA requires FDA to reconsider the approach in the Seafood HACCP Rule of exempting carriers from direct regulatory coverage.

[21] §117.130(c)(3)(iv).

FDA states in the Preventive Controls for Human Food Rule: "We do not expect a future rulemaking implementing the SFTA to eliminate the need for the owner, operator, or agent in charge of a facility to consider transportation practices when determining whether a hazard is reasonably likely to occur."[22] FMI seeks greater detail as to how FDA believes importers must consider transportation practices following the implementation of SFTA regulations. FMI furthermore urges the Agency to contemplate issues regarding rejections of produce shipments for quality reasons pursuant to the Perishable Agricultural Commodities Act in crafting both the FSVP and SFTA regulations.

V. Various

Qualified Individual

FMI believes that the term qualified individual should be sufficiently flexible as to encompass individuals in the food safety/quality assurance and legal departments of food retailers and wholesalers who possess significant experience in food safety matters and should not include additional arbitrary requirements that would disqualify such individuals from performing such tasks. For example, a qualified individual for purposed of the FSVP or Preventive Control regulations should not need the same type of experience as an individual qualified as an audit agent to perform food safety audits pursuant to the Accreditation of Third-Party Auditors regulations. FMI believes the current definition maintains such flexibility.

Testing Standards

FDA has concluded in the Proposed Rule that it is not appropriate to specify standards of testing in the regulation. FMI agrees with the Agency. FMI strongly believes that all standards should be based on the latest scientific research available and for that reason they should be in guidance documents and not the regulation itself. This premise applies scientific standards, analytical methods, indicator organisms, and pathogens of concern. If FDA requires any of these in the FSVP regulations, FMI recommends that FDA refer to guidance where the appropriate technical and scientific standards can be made available to the industry and changed with advances in science.

[22] 78 Fed. Reg. 3737 (January 16, 2013).

Employees of Foreign Governments

FDA intends to permit importers to rely on certain activities of foreign government employees of both accredited and unaccredited government entities as qualified individuals. FMI believes allowing importers to rely on certain activities of employees of both accredited and unaccredited government entities, such as onsite audits and inspections could reduce the burdens of compliance.

Interplay of FSVP and Preventive Controls Rules

In many instances, domestic food facilities will be importing ingredients. If a domestic food facility is in compliance with supplier verification under the Preventive Controls Rules, it should be deemed to be in compliance with FSVP regulations that address the same matters.

Supplier Approval and Verification Under Preventive Controls Rule: Only Importer Should Bear Burden of Foreign Supplier Verification

FDA asks, would it be appropriate for the FSVP rules to state that an importer whose customer is required to establish a supplier approval and verification program under the Preventive Controls Rule is deemed to be in compliance with the FSVP regulations? FMI disagrees with the premise of this question. **Only one verification should be required and it should be conducted by the entity that is deemed to be importer under the FSVP.** The Preventive Controls Rules should not extend to foods imported by a separate importer who is in compliance with FSVP. Under any supplier verification component in the Preventive Controls Rules, a retailer or other customer of an importer should only need an assurance from the importer it is purchasing from that the importer is in compliance with the FSVP regulation.

If the importer itself is subject to the Preventive Controls Rules, compliance with those rules should satisfy any duplicative aspects of FSVP.

Hazards Controlled by Customers of Importers

In many instances importers may import a product without knowing who their customer will be at the time of entry—for example if there is no U.S. purchaser at the time of entry. FDA should consider this in drafting the FSVP regulations. The Agency should

contemplate permitting products with uncontrolled hazards that are normally subject to additional control steps where hazards will be controlled before being offered for sale to consumers as an ingredient of a food, or the food itself, to be imported absent an assurance from a specific customer of an importer. FDA should consider developing a list of products that meet such criteria.

Recognition of Foreign Food Safety Systems

Imports from countries with officially recognized or equivalent food safety systems are generally exempt from most requirements of the Proposed Rule. To date, the only country recognized by FDA is New Zealand. Recognition of other countries has the potential to significantly reduce burdens on importers. FMI urges FDA to act expeditiously on applications of foreign governments for such recognition and encourages the Agency to conduct outreach to educate the international community on this aspect of the Proposed Rule and others that are applicable to foreign governments and foreign exporters.

FDA Should Incorporate § 1.513 in any Domestic Supplier Verification Program

FDA has stated that it intends to align any supplier verification requirement contained within the proposed Preventive Controls Rules with the FSVP regulations.[23] FMI notes that if this is indeed the case, FDA should exempt firms sourcing from U.S. food facilities and growers from conducting supplier verification activities much as it will with products from New Zealand suppliers. If FDA does not take such action, it would be requiring that greater supplier verification activities be conducted for U.S. grown and produced food than for food of New Zealand. In requiring full domestic supplier verification for U.S. growers and producers, FDA would be effectively taking the irrational position that the U.S. food safety regulatory system is not comparable or equivalent to itself. Instead, under any domestic supplier verification program, FDA should apply a provision equivalent to § 1.513 to firms sourcing from U.S. growers and producers.

[23] 78 Fed. Reg. 3767.

Draft Guidance

FDA states that it plans to issue draft guidance to provide importers with recommendations on how to comply with the various aspects of the FSVP requirements concurrently with the final rule because the Agency believes that this will facilitate more meaningful review and comment. FMI agrees with the Agency.

Section 1.502 requires importers, for each food they import to "develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety)."[24] FMI urges the Agency in said draft guidance to provide clarity to importers as to what constitutes "at least the same level of public health protection."

List of Importers

Pursuant to 21 USC 384a(g), FDA is required to publish a list of importers participating in FSVP. The Agency is required to include the name of, location of, and "other information deemed necessary by the Secretary" about importers participating in FSVP.[25] FMI supports this provision of FSMA and urges the Agency to publish the list expeditiously following implementation of the Proposed Rule. The list will be helpful to retailers and others who seek to source from or otherwise employ the services of such importers. FMI seeks greater clarity from FDA as to what information will be "deemed necessary." FMI believes an indication of the compliance status of the importer would be a helpful data point to provide.

Review of Complaints

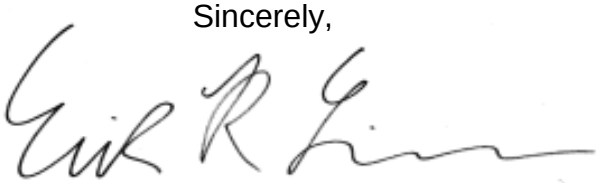
Under § 1.507, importers must promptly conduct a review of any customer, consumer, or other complaint received to determine whether the compliant relates to the adequacy of the importer's FSVP. Grocery retailers receive tens of thousands of complaints from consumers each year. Most complaints relate to product quality rather than safety. Retailers proactively deal with such complaints. Complaints are generally managed at the retail level. FMI seeks greater clarification as to what constitutes a valid complaint. The obligation to investigate complaints should be limited only to those that are related to food safety and not quality issues. FDA enforcement of this section should be

[24] 78 Fed. Reg. 45774 (July 29, 2013).
[25] 21 USC 384a(g).

focused on the adequacy of the program for review of complaints and appropriate corrective actions rather than inspection of individual complaint response.

We appreciate your consideration of these comments. Please do not hesitate to contact me at elieberman@fmi.org or (202) 810-4044 if you have any questions.

Sincerely,



Erik R. Lieberman
Vice President and Chief Regulatory Counsel